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(56) Documents cited

None

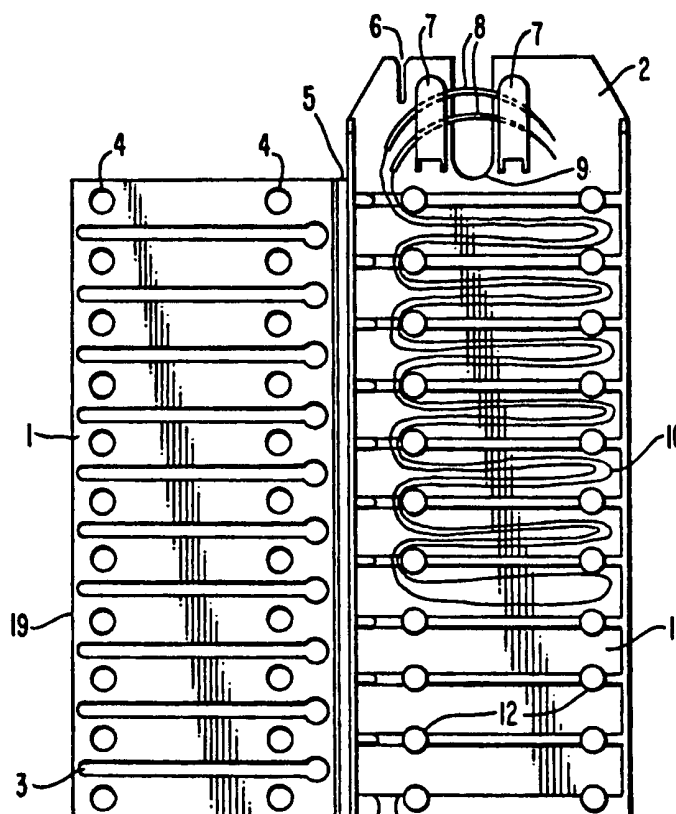
(58) Field of search

B8C
B8P

(57) A dispensing pack for surgical sutures

(54) A dispensing pack for needled sutures comprises a moulded plastics cover panel 1 hinged to a compartmented base panel 2 within which the or each suture 10 extends in a sinusoidal manner between the interconnected compartments 11. One or more needles are mounted in supports 7 to extend across a recess 9 in an end portion of panel 2, this end portion extending beyond the cover panel 1 after closure of the pack. Studs 12 on panel 2 engage in corresponding apertures of panel 1 to lock the panels 1 and 2 when closed.

FIG. 1.



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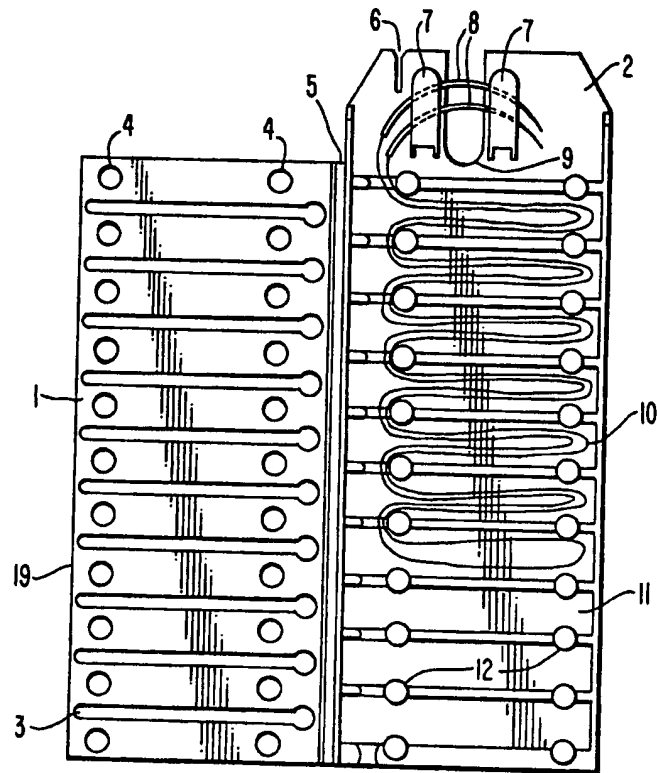
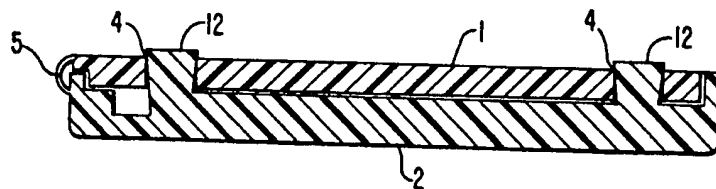
FIG. 1.**FIG. 1A.**

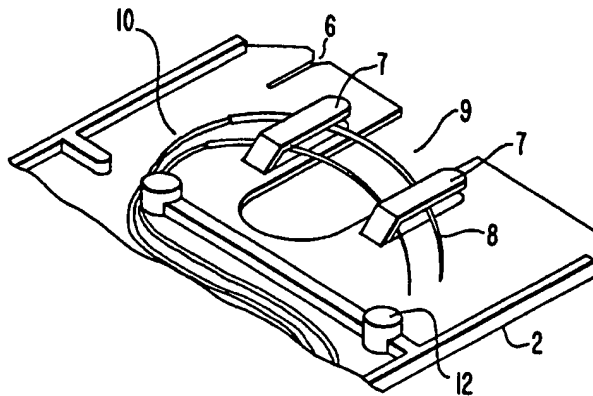
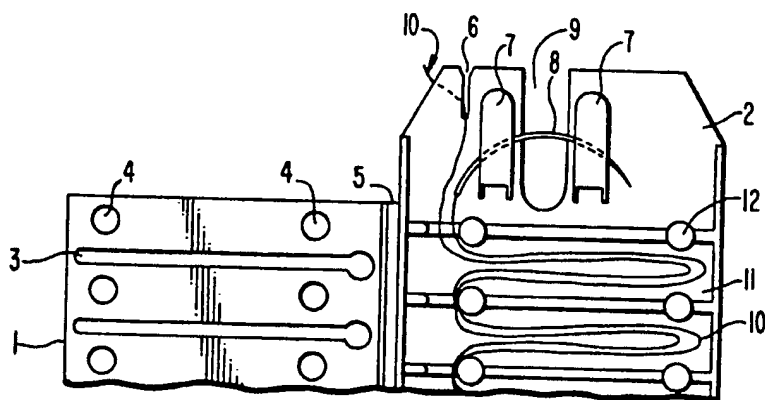
FIG. 1B.**FIG. 1C.**

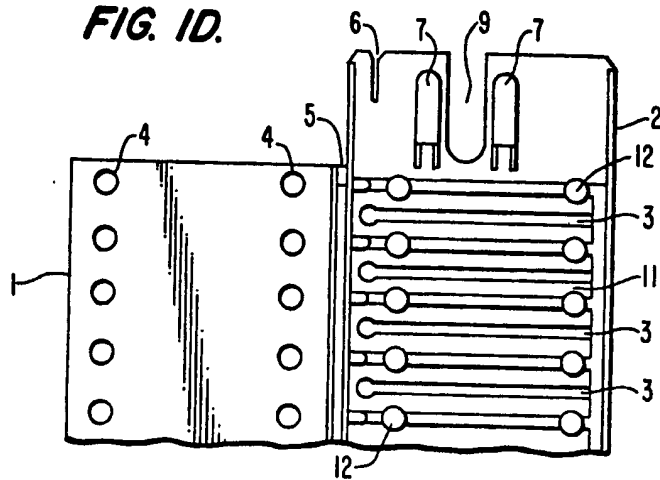
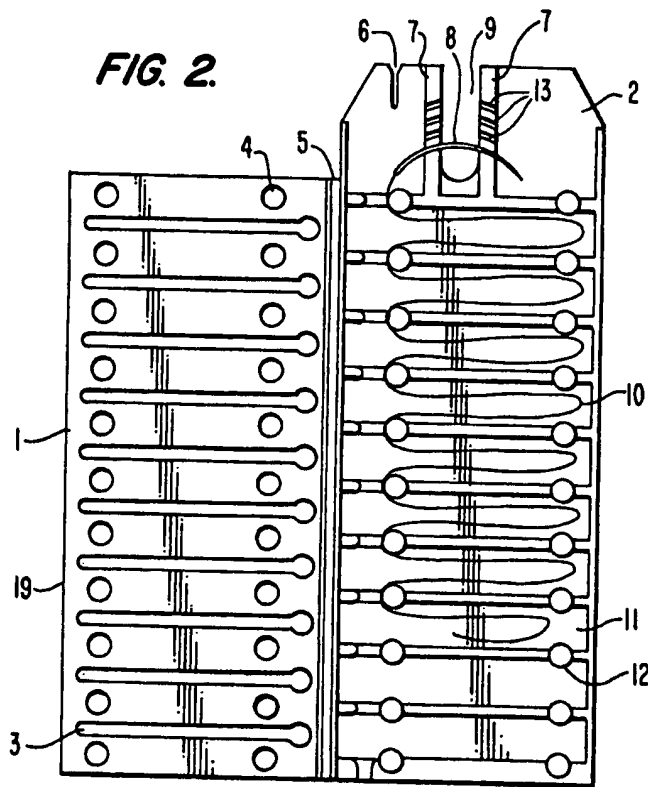
FIG. 1D.**FIG. 2.**

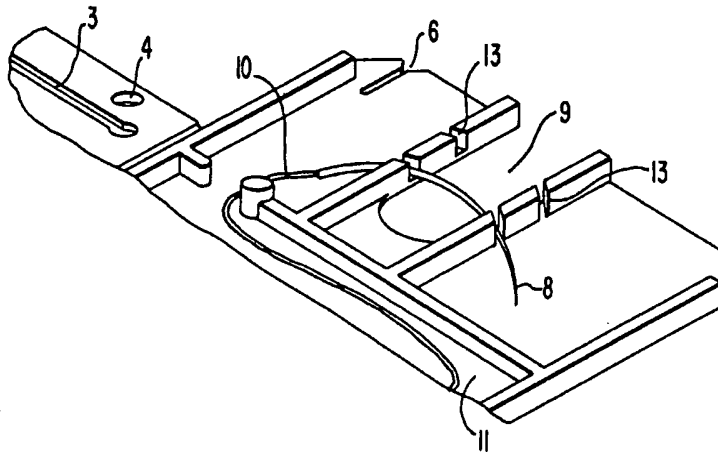
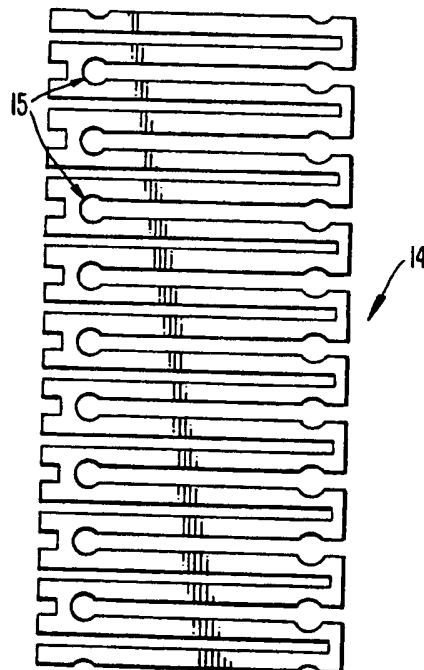
FIG. 2A.**FIG. 3.**

FIG. 3A.

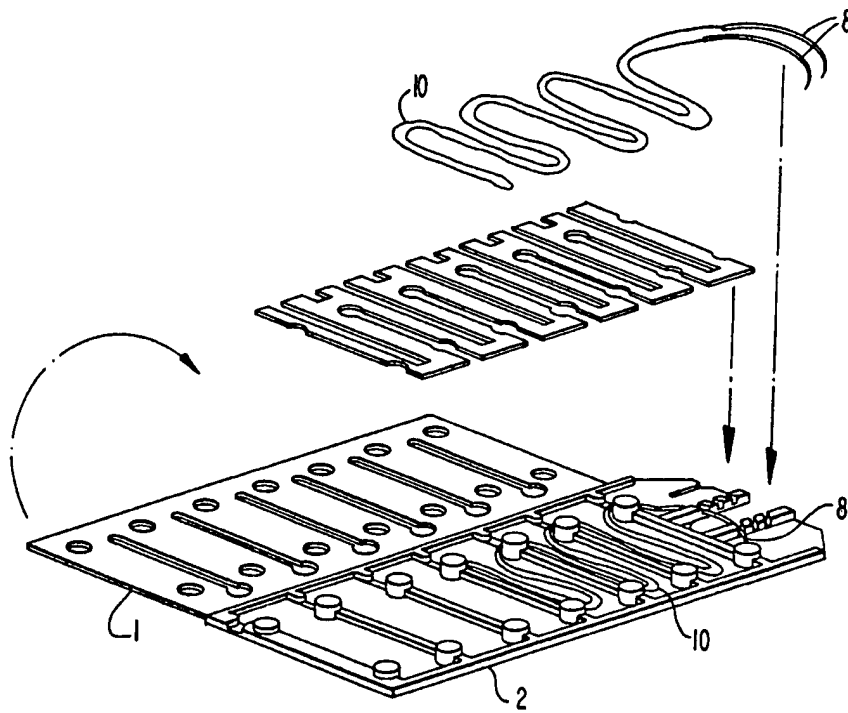
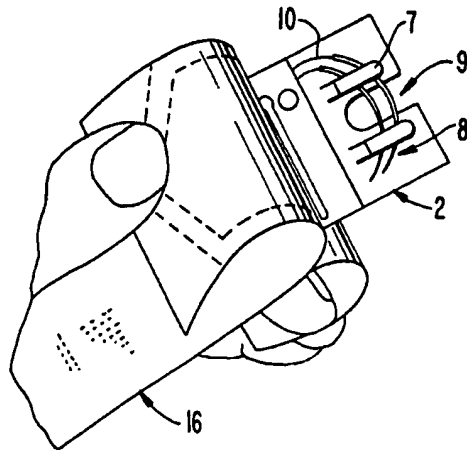
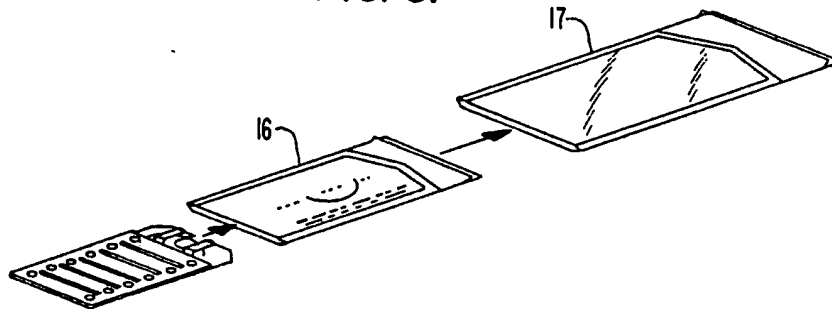


FIG. 4.**FIG. 5.**

SPECIFICATION

A dispensing pack for surgical sutures

- 5 This invention relates to a dispensing pack for surgical sutures.

Packages for surgical sutures having needles attached at one or both ends are constructed according to the nature of the suture material and to how the sutures will be used.

Generally, the package holds the suture and attached needles in place, protects them during handling and storage, and allows ready access to the suture for removal with minimum handling at the time the suture is to be used. The suture should also be removable without becoming entangled with itself, kinked or coiled in undesired ways. The nature of the suture material itself may impose limitations on the configuration of the package, how the suture is placed within the package, the placement of the needles, or how the suture is drawn from the package.

25 A frequently used form of package consists of a folded stiff treated paper suture holder contained in a sterile, hermetically sealed envelope, which envelope is further sealed in a second, usually clear, thermoplastic heat-sealed envelope outer wrap to maintain the suture holder and inner envelope sterile. When the suture is to be used, the outer clear wrap is opened in the operating room and the sealed sterile inner envelope deposited in a sterile area. Sterile personnel then open the inner envelope when access to the suture is needed.

Many of the prior packages are not suitable in that crimping, flattening, tangling, or knotting may occur during loading, handling, or removing a PTFE suture from the package.

Additionally, although many suture packages attempt to fix any attached needles in a particular location for easy presentation to the user, it has been found that often the needles become dislodged and are not conveniently presented to the user. If the needles do remain fixed in place, they are often accessible from one direction only.

50 According to the present invention there is provided a dispensing pack for surgical sutures comprising:

- (a) a first panel forming a closure hingedly affixed to
- 55 (b) a second panel having integrally molded interconnected compartments for protectively holding said sutures,
- (c) a recess extending inwardly from an edge of the second panel,
- 60 (d) a needle-supporting means adjacent said recess for supporting needles attached to said sutures so that the needles extend across said recess, and
- (e) locking means integrally molded in said
- 65 panels for interlocking said panels upon clo-

sure, the dimensions of said panels being such that the needle-supporting means are disposed beyond said first panel upon closure.

70 By means of the suture dispensing pack according to this invention several advantages over prior art packages for PTFE sutures can be secured. The advantage of non-overlapping of PTFE suture strands can be secured by locating the suture in a sinusoidal manner as it extends between the interconnected compartments, and it can be drawn out without opening the panels of the pack. This is combined with holding of the needles in a fixed position in a unique orientation which presents the needles in such a way that they may be gripped from either side of the package by a needle holder. Right-handed or left-handed removal of the needle and suture is equally facile. The needles can be rendered immediately visible in the top of the pack on only a partial peeling back of a protective envelope and can be immediately gripped in the recess from either side of the pack and the suture easily withdrawn from the pack without further opening of the protective envelope.

In a preferred embodiment of the invention, the pack is molded in plastics material and has a first panel connected by molded plastic hinges along a major edge to a second panel along a portion of a major edge. Both panels and the connecting hinges are molded simultaneously as one piece. The first panel is flat and has linear access slots extending across the width of the panel disposed at even predetermined distances apart down its length with holes spaced in between the slots so as to receive and hold the tops of studs at the ends of dividers which form suture holding compartments in the second panel.

105 The second panel is longer than the first panel, the needle-holding portion extending beyond the first panel, has chamfered upper corners to ease insertion of the loaded folded pack into a protective envelope, an optional suture retainer slot cut into the left end of the upper edge, a U-shaped recess disposed in the centre of the upper edge, two plastic needle clips or holders disposed one on each side of the U-shaped recess and, evenly disposed below the U-shaped recess and needle clips, a series of interconnected separate molded suture compartments arranged on an even predetermined spacing in registration with the slots of the first panel when the first panel is folded over the second panel. The studs are slightly tapered (optionally) and extend above the surface of the second panel so as to penetrate the holes provided in the first panel on closure of the pack to hold the first panel firmly to the face of the second panel by tight pressure fit in the holes.

125 On loading, the needles attached to the suture are fixed in place across the U-shaped notch of the second panel behind the clips or in a set of slots, the suture disposed along the

space provided along the interconnection channel of the suture compartment, the first panel folded over to cover the suture compartment of the second panel and affixed in place by interlocking tongue and groove or other suitable means molded into the edges of the two panels, as well as or as an alternative to the studs of the second panel fitting the holes in register with them on the first panel, and the suture disposed in sinusoidal configuration in the suture compartments with utilization of the access slots of the first panel.

The needle point always faces to the right, away from the suture channel into the suture holding compartments.

The invention will now be particularly described by way of example with reference to the accompanying drawings in which:

Figure 1 is a front plan view of an unfolded plastic pack according to the invention shown containing a suture with a needle attached at each end, and showing compartments of the pack separated by dividers;

Figure 1A is a cross-sectional view of the pack taken through one divider between compartments, the pack being shown closed and locked;

Figure 1B is a broken perspective view of an end portion of the pack in which suture-bearing needles are shown held by integral plastic clips;

Figure 1C is a plan view of the end portion of the end portion of the pack showing a single needle with suture held by the plastic clips and the free end of the suture held in a slot in the end of the pack;

Figure 1D is a plan view of an end portion of a modified pack;

Figure 2 is a plan view of an alternative embodiment of the pack showing a suture bearing one attached needle, the needle held in place in a pair of slots formed at an end of the pack;

Figure 2A is a perspective partial view of the end of the pack of Figure 2 showing a needle held in a pair of slots;

Figure 3 is a plan view of a thin plastics separator which can be used to separate sutures in a multiplyloaded pack.

Figure 3A is an exploded perspective view of a multiply-loaded pack with one suture disposed on a base panel of the pack, one separator to be placed on it, and another suture to be placed on the separator;

Figure 4 is a perspective view of the end portion of a pack showing a partially peeled back inner protective envelope with the suture pack displaying the needles in readily available position; and

Figure 5 is a perspective view showing a plastic suture pack being inserted into an inner protective envelope which, after sealing is inserted into an outer clear envelope which is also sealed.

Referring now to the drawings, identical

numerals are used for identical parts in each of the figures to aid in the description of the suture pack of the invention. Figure 1 shows in unfolded configuration (as it was molded) a two panel plastics pack according to the invention. The first panel 1 forms a cover which is joined by one or more integrally molded plastic hinges 5 to a second panel 2 which forms a base. When the cover panel is folded over on to base panel 2, it covers the suture holding compartment within the base panel 2 but leaves exposed the end portion of the base panel. This end portion contains clips 7 in which needles 8 are supported so that they extend across a U-shaped recess 9 in the end of panel 2.

The first panel 1 has a series of spaced slots 3 extending across its width at predetermined spacings with holes 4 disposed between the slots 3. Slots 3 extend fully through panel 1. The holes 4 are in register with the molded studs 12 located adjacent the ends of dividers between the suture holding compartments 11 so that a tight pressure fit is obtained when the pack is closed and the two panels are held firmly together. Stud 12 are slightly tapered to assure firm holding in the holes 4.

The second panel 2 has an edge slot 6 which may optionally be utilized to anchor the end of a suture, the slot 6 extending parallel to the U-shaped recess 9. The clips 7 for supporting the needles 8 may be punched out from the body of panel 2 or optionally molded in place as panel 2 is being molded. A suture 10 extending between needles 8 is shown disposed in a sinusoidal configuration the suture lying in a long loop in each compartment and extending from each compartment 11 to the next via a slot at one end of each of the compartment dividers. Accordingly, upon removal of a needle from its supporting means, the suture can be drawn out of the pack without opening the pack.

Adjacent the ends of the dividers between suture holding compartments 11, the studs 12 are molded to extend above the surface of the remainder of panel 2 and extend slightly above the outer surface of panel 1 when in closed position covering a portion of the face of panel 2.

To close the pack, panel 1 is folded over on to panel 2 and locked by engagement of the studs 12 in the holes 4 as seen in Figure 1A. Panel 1 is shown optionally hinged 5 to panel 2.

Figure 1B shows more clearly how a pair of needles 8 attached to a suture 10 are held by the pair of integral plastic clips 7 across the recess 9 so that the needles can be conveniently reached for easy removal from either side of recess 9 of the pack, for example by a pair of forceps inserted into the recess to engage and grip a needle.

As an alternative to twin needles, the suture

can extend from a single needle and the free end of the suture received in the slot 6 shown in Figures 1B, 1C and 1D.

Figure 1D depicts an alternative location for the thru-slots 3, namely at the bottom of the suture holding compartments 11 of panel 2 instead of in panel 1.

In the alternative embodiment of Figures 2 and 2A, ribs are molded along opposite sides of the recess 9 to contain pairs of shaped slots 13 which extend in predetermined curves across U-shaped recess 9, the curves chosen to match the curvature of the needles 8 to be placed in the pack. Where multiple sutures with attached needles are to be packaged, it is necessary in the case of PTFE sutures, for which the packs of the invention are designed, to be spaced apart from each other within the suture holding compartment 11 by thin plastic separators 14 as shown in Figure 3. The separators 14 contain slots extending alternately from opposite sides of the separator to give a serpentine or zig-zag configuration, one set of alternate slots containing apertures or enlargements 15 for engagement over the studs 12 of the base panel 2. The separators 14 are held in place in compartment 11 by careful sizing and registration of the enlargements 15 with the studs 12.

In the exploded perspective view of Figure 3A, the panels 1 and 2 are generally as shown in Figure 2 and one suture 10 is shown loaded in the pack, a thin plastics separator located above it, and the next suture to be loaded into the pack. The needles attached to this next suture would be disposed in an open shaped slot beyond that depicted as holding the needles of the first suture in place.

Figure 4 shows a pack according to the invention in which the needles 8 are exposed for ready use by partially peeling back a protective envelope 16. The needles 8 are completely visible either on the side of the pack on which they are held in place or through the transparent plastic panel 2 of the pack.

Figure 5 shows a suture and needle-loaded pack according to the invention which is ready to be placed inside inner protective envelope 16. Envelope 16 is sealed, then inserted inside clear outer protective envelope 17, envelope 17 is sealed, the packaged packs are cartoned, and then sterilized with, for instance, ethylene oxide gas. Printed indicia regarding contents and instructions for use can be disposed on the inner protective envelope 16.

The plastics suture pack can be manufactured from injection moldable plastics known in the art, such as polypropylene, polyethylene, polysulfone and other polymers. The suture separators utilized with multiple suture loadings may be cut from plastic sheets or

molded from common plastics such as those cited above. The inner and outer protective envelopes are usually of heat sealable thermoplastic polymers, such as, for instance, polyethylene, polypropylene, polyvinyl acetate-ethylene copolymer, or Tyvek (DuPont de Nemours trademark) diolefin polymer, which may also be in the form of composites with paper, aluminum foil, or other appropriate materials. It is preferred that the inner envelope be a composite bearing any required printed indicia and that the outer envelope be of a clear heat-sealable thermoplastic material. The porous expanded polytetrafluoroethylene utilized as suture material is that referred to above, and manufactured by W.L. Gore & Associates, Inc.

CLAIMS

1. A dispensing pack for surgical sutures comprising:

(a) a first panel forming a closure hingedly affixed to

(b) a second panel having integrally molded interconnected compartments for protectively holding said sutures,

(c) a recess extending inwardly from an edge of the second panel,

(d) needle-supporting means adjacent said recess for supporting needles attached to said sutures so that the needles extend across said recess, and

(e) locking means integrally molded in said panels for interlocking said panels upon closure, the dimensions of said panels being such that the needle-supporting means are disposed beyond said first panel upon closure.

2. A pack according to claim 1 wherein a separator shaped to correspond approximately to that of said suture holding compartments is disposed between two sutures disposed in said compartment.

3. A pack according to claim 1 having therein a suture attached to at least one surgical needle.

4. A pack according to claim 3 wherein the suture is comprised of porous expanded polytetrafluoroethylene.

5. A pack according to any preceding claim wherein the compartments are separated by dividers, each divider having a slot adjacent one end thereof through which the compartments are interconnected and through which the suture can extend between compartments in a sinusoidal manner.

6. A pack according to any preceding claim wherein elongate slots are molded into the first panel of said pack to correspond with each of said compartments.

7. A pack according to any preceding claim wherein the needle-supporting means comprises integrally formed plastics clips on either side of said recess.

8. A pack according to any one of claims 1 to 6 wherein the needle-supporting means comprise pairs of curved slots disposed on

either side of said recess.

9. A pack according to any preceding claim wherein said interlocking means comprises shaped apertures disposed in a predetermined pattern in portions of said pack which fit over and interlock with integrally molded studs of a corresponding shape to said apertures disposed to register with said apertures on other portions of said pack when said panels of the pack have been folded together.

10. A pack according to any preceding claim which has been sealed into one or more plastic protective envelopes and the whole sterilized.

11. A pack according to any preceding claim which has been molded from polypropylene, polyethylene, polysulfone, polystyrene or copolymers of styrene, polyvinyl chloride, acrylonitrile-butadiene-styrene polymers, acrylics, cellulosics, polyamide polymers, acetal, polycarbonate, fluoroolefin polymers, or silicone rubber.

12. A pack substantially as, and for the purpose, herein described with reference to the accompanying drawings.